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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,394	06/02/2005	Francois Romagne	INN-123	8478
23557 7590 02/04/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER SZNAIDMAN, MARCOS L				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
02/04/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/537,394

**Applicant(s)**

ROMAGNE ET AL.

**Examiner**

MARCOS SZNAIDMAN

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 80-103 is/are pending in the application.
- 4a) Of the above claim(s) 89-96-99 and 103 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 80-88-90-95 and 100-102 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This office action is in response to applicant's reply filed on November 19, 2008.

#### ***Status of Claims***

Claims 80-103 are currently pending and are the subject of this office action.

Claims 89, 96-99 and 103 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 19, 2008.

Claims 80-88, 90-95 and 100-102 are presently under examination.

#### ***Priority***

The present application is a 371 of PCT/IB03/06375 filed on 10/02/2003, and claims priority to EPO 02292963.2 filed on 12/02/2002.

#### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 102 (Maintained Rejection)***

Claims 80-88, 90-95 and 102 stand rejected under 35 U.S.C. 103(a) as being unpatentable over BioNews ([http://www.investinbiotech.com/pressroom\\_release.php?id+644](http://www.investinbiotech.com/pressroom_release.php?id+644), July 8, 2002) as evidenced by Espinosa et. al. (Journal of Biological Chemistry (2001) 276:18337-18344).

Claims 100-101 stand rejected under 35 U.S.C. 103(a) as being unpatentable over BioNews ([http://www.investinbiotech.com/pressroom\\_release.php?id+644](http://www.investinbiotech.com/pressroom_release.php?id+644), July 8, 2002) as evidenced by Espinosa et. al. (Journal of Biological Chemistry (2001) 276:18337-18344) as applied to claims 80-88, 90-95 and 102 above, and further in view of Negrier et. al. (The New England Journal of Medicine, (1998) 338:1272-1278).

The reasons for this rejection have been provided in the previous office action dated May 23, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that the reference of BioNews is not prior art to the claimed invention. Applicant submitted a Declaration under 37 C.F.R. 1.131 antedating the BioNews reference. As stated in the Declaration, the claimed invention was conceived

and reduced to practice prior to the critical date (July 8, 2002) in France, a WTO member state.

Examiner's response: The declaration filed on November 19, 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the BioNews reference. The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of BioNews reference (July 8, 2002). While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the BioNews reference to either a constructive reduction to practice or an actual reduction to practice. The evidence submitted is insufficient to establish applicant's alleged actual reduction to practice of the invention in this country or a NAFTA or WTO member country after the effective date of the BioNews reference. The declaration filed on November 19, 2008 discloses a Phase I/II study aimed primarily to determine the maximum-tolerated dose of INNACELL GD (a gamma-9-delta-2cell therapy product) in the treatment of patients with metastatic renal carcinoma (MRCC). INNACEL is manufactured in vitro from an autologous peripheral blood mononuclear cell (PBMC) preparation, by a single stimulation with Phosphostim (BrHPP). In other words: Phosphostim is not being used to treat renal carcinoma, but to manufacture a INNACELL, which then is administered to patients with renal carcinoma.

There is no mention in the entire Declaration of a method of treating renal carcinoma with Phosphostim (BrHPP).

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
January 28, 2009

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612